PRENATRIX- ferrous fumarate, folic acid tablet
PureTek Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Prenatrix

DESCRIPTION:

\Each caplet contains:

Vitamin A (as retinyl acetate)…….. 1500 mcg
Vitamin C (as ascorbic acid)…… 120 mg
Vitamin D3 (as cholecalciferol)…… 20 mcg
Vitamin E (dl-alpha tocopheryl acetate)…… 30 mg
Thiamin (as thiamine mononitrate)…… 3 mg
Riboflavin (vitamin B2)……. 3.4 mg
Niacin (as niacinamide)…… 20 mg
Vitamin B6 (as pyridoxine hydrochloride)……. 50 mg
Folate (as folic acid)…….. 1700 mcg DFE (1000 mcg folic acid)
Vitamin B12 (as cyanocobalamin)…… 10 mcg
Choline (as Choline Bitartrate)…….. 55 mg
Calcium (as calcium carbonate)……. 200 mg
Iron (as ferrous fumarate)…… 27 mg
Iodine (as potassium iodine)…….150 mcg
Magnesium (as magnesium oxide)…… 200 mg
Zinc (as zinc oxide)…….. 25 mg
Selenium (as selinium amino acid chelate)……. 70 mcg
Manganese (as manganese sulfate)…… 2.6 mg
Chromium (as chromium polynicotinate)…….. 45 mcg
Molybdenum (as molybdenum amino acid chelate)…… 50 mcg

Other Ingredients: BHT, dicalcium phosphate, croscarmellose sodium, crospovidone, magnesium stearate, medium chain triglycerides, microcrystalline cellulose, modified food starch, pork gelatin, starch aluminium octenyl succinate, sodium ascorbate, sodium aluminum silicate, silicon dioxide, stearic acid, sucrose, Clear Coating: (hydroxypropyl methylcellulose, PEG-8).

Indications

Prenatrix is indicated to provide vitamins and minerals to women throughout pregnancy and during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years.
Prenatrix may be beneficial in improving the nutritional status of women prior to conception.

Contraindications:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with

hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNING

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.
Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

Precautions

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call PureTek Corporation at 1-877-921-7873 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

Prenatrix is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin or Clopidogrel).

Adverse Reactions:

Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.
Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving Prenatrix after meals may control occasional gastrointestinal disturbances. Prenatrix is best absorbed when taken at bedtime. Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

OVERDOSE:

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis,melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Prenatrix should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs out of reach of children.

Treatment:

For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

Dosage and Administration:

Adults (persons over 12 years of age) One (1) Prenatrix caplet
daily, between meals or as directed by a physician. Do not administer to children under the age of 12.

HOW SUPPLIED

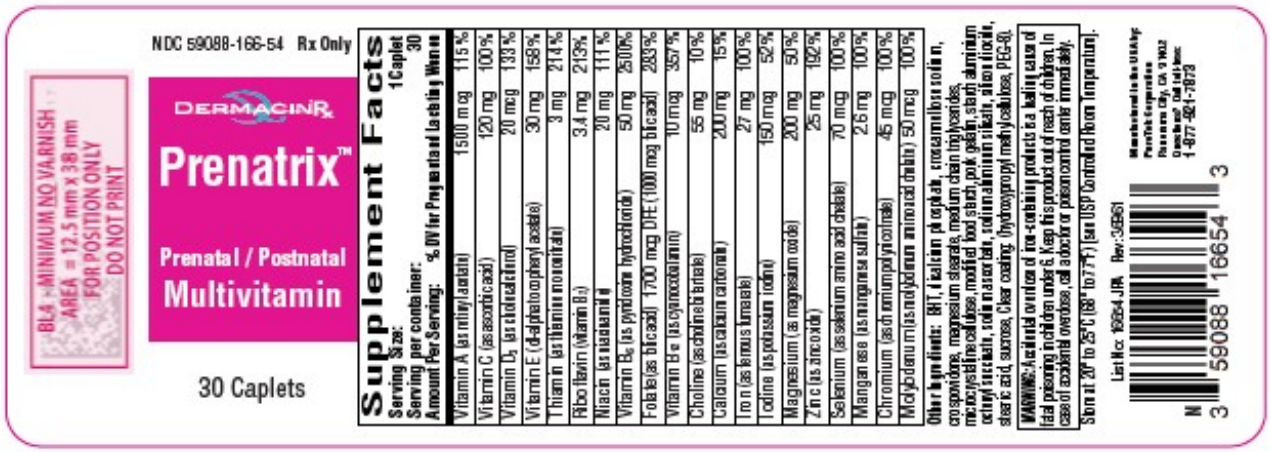
Prenatrix are yellow to brown speckled, oblong, coated caplets with "PT A18" debossed horizontally on one side,
bottles containing 30 caplets – NDC 59088-166-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.
Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

Storage

Do not use if bottle seal is broken.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP].
Protect from light and moisture and avoid excessive heat.
To report a serious adverse event or to obtain product information, contact 877-921-7873.

Prenatrix

Manufactured by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: 877-921-7873



PRENATRIX

ferrous fumarate, folic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-166
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.6 mg
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	50 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	50 ug
CHOLINE BITARTRATE (UNII: 6K2W7T9V6Y) (CHOLINE - UNII:N91BDP6H0X)	CHOLINE	55 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	45 ug
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	70 ug
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 ug

Inactive Ingredients

Ingredient Name	Strength
SODIUM ASCORBATE (UNII: S033EH8359)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GELATIN (UNII: 2G86QN327L)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SUCROSE (UNII: C151H8M554)	
CROSPOVIDONE (UNII: 2S7830E561)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM ALUMINIUM SILICATE (UNII: 058TS43PSM)	

Product Characteristics

Color	yellow (Clear Coated Yellow to Brown speckled)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	PT;A18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-166-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/29/2020	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	label(59088-166) , manufacture(59088-166) , pack(59088-166) , relabel(59088-166)